

REMARKS

Reconsideration is requested.

Claims 35, 36 and 43-67 are pending.

Claim 35 has been amended, as suggested by the Examiner, to specify that the vector is suitable for *in vitro* transgene delivery into mammalian cells. See Office Action dated May 17, 2006. This amended claim further specifies that **each** of the two distinct posttranscriptional regulatory elements comprises a UTR region of a eukaryotic mRNA selected from a WPRE element, tau 3'UTR, TH3'UTR and APP5'UTR.

This amended claim is supported, for example, by unamended claim 35 and by pages 3 (lines 3-5), 8 (lines 6-11) and 11 (lines 13-14) of the specification. No new matter has been added.

Claims 43-46 depend from pending claims.

Amended claims 53, 54 and 58 have been clarified as requested by the Examiner. These amended claims do not include new matter.

Amended claims 64-67 now specify that the claimed method is for expressing *in vitro or ex vivo* a transgene in cells. These amended claims are supported, for example, by page 4 (lines 10-16) of the specification.

These amendments are made without prejudice or disclaimer and solely in order to facilitate reconsideration of this application. In particular, applicant reserves his right to file a divisional application at a later stage, and the present amendment shall not be considered as an admission of the objection or as a waiver of any subject matter.

Withdrawal of the objection to claims 43-46 is requested in view of the above amendments.

Withdrawal of the Section 112, second paragraph, rejection of claims 43-46 and 53-56 is requested in view of the above amendments.

To the extent not obviated by the above amendments, the Section 112, first paragraph "written description", rejection of claims 35, 38-39, 43-46 and 64-67, and the Section 112, first paragraph "enablement", rejection of claims 35, 38-38, 43-46, 54-56 and 64-67, are traversed. Reconsideration and withdrawal of the rejections are requested in view of the above and the following comments.

Amended claim 35 now specifies that the vector is suitable for *in vitro* transgene delivery into mammalian cells. It further specifies that **each** of the two distinct posttranscriptional regulatory elements comprises a UTR region of a eukaryotic mRNA selected from a WPRE element, tau 3'UTR, TH3'UTR and APP5'UTR. The amended method claims require an *in vitro* or *ex vivo* expression of a transgene.

As is believed to have been acknowledged by the Examiner, the specification is enabling for a vector comprising a transgene operably linked to at least two distinct postrancriptionnal regulatory elements comprising UTR regions selected from WPRE, APP, tau and TH elements suitable for transgene delivery to mammalian cells, and methods for expressing a transgene in mammalian cells *in vitro*, using said vector.

The claims are believed to be supported by an adequate written description which teaches one of ordinary skill how to make and use the claimed invention. One of ordinary skill will appreciate the applicants were in possession of the claimed invention, and that the specification teaches how to use the claimed invention, without requiring recitation of specific postrancriptionnal regulatory sequences, as the description explains that the functions of these sequences were known in the art (see for example

page 2 of the specification). Such a recitation in the claims may therefore unduly limit their scope when compared with the teaching provided in the present specification.

Withdrawal of the Section 112, first paragraph, rejections is requested.

The Section 102 rejection of claims 53-56 over Barsov (U.S. Patent Application Published No. 2002/0110896), is obviated by the above amendments as claims 53-56 do not encompass a recombinant cell comprising any chimeric genetic construct and a composition comprising any chimeric genetic construct for treating a human neurodegenerative disease. The reference fails to teach each and every aspect of the claimed invention. Withdrawal of the Section 102 rejection is requested.

The following Section 103 rejections are traversed:

the Section 103 rejection of claims 35, 37-38 and 46 over Barry (Human Gene Therapy 12:1103-1108; 2001) in view of Paulding (JBC 274:2532-2538),

the Section 103 rejection of claims 39 and 43 over Barry, Paulding and Ramezani (Molecular Therapy 2:458-469; 2000),

the Section 103 rejection of claims 40, 44 and 64-65 over Barry, Paulding, Ramezani and Rogers (JBC 274:6421-6431; 1999),

the Section 103 rejection of claims 41-42, 45 and 66-67 over Barry, Paulding, Ramezani, Rogers and Aronov (J. Mol. Neurosci., 12:131-145; 1999), and

the Section 103 rejection of claims 52, 56 and 59 over Barry and Chang (Curr. Gene Ther. 2:237-251; 2001).

Reconsideration and withdrawal of the Section 103 rejections are requested in view of the following distinguishing comments.

The applicants believe that Barry et al., does not describe a vector wherein each of the two distinct posttranscriptional regulatory elements comprises a UTR region of a eukaryotic mRNA selected from a WPRE element, tau 3'UTR, TH3'UTR and APP5'UTR. The inventors have tested combinations of these posttranscriptional regulatory elements and unexpectedly found that they could cooperate or synergize to provide positive effects on transgene expression. The cited prior art is not believed to teach or suggest that enhancements of expression are observed when at least two of the above identified distinct posttranscriptional regulatory elements are combined in a vector according to the invention (see page 6, line 25 to page 9, line 28 and pages 20-28 of the experimental part for example). The secondary references are not believed to cure these deficiencies of the primary reference.

Withdrawal of the Section 103 rejections is requested.

The claims are submitted to be in condition for allowance and a Notice to that effect is requested.

The Examiner is requested to contact the undersigned in the event anything further is required.

MALLET et al
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Amendment

Respectfully submitted,

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